

To: Our Clients and Friends

March 17, 2009

## Wyeth v. Levine: U.S. Supreme Court gives unprecedented power to state tort juries, rather than the Food and Drug Administration, to regulate warning labels for prescription drugs.

According to the U.S. Supreme Court in Wyeth v. Levine, Food and Drug Administration (FDA) approval of labels providing warnings about the effects of drugs does not pre-empt lawsuits under state law claiming inadequate warnings of a health risk.

The plaintiff in this case presented at a Vermont health clinic with a severe migraine headache and associated nausea and dehydration. She was initially administered an intra-muscular injection of Wyeth's anti-nausea drug, Phenergan, but returned later in the day and was given an "IV-push" intravenous injection (as opposed to an "IV-drip") of additional Phenergan. Due to carelessness or mistake of the clinic staff, the plaintiff developed complications from the injection when the drug inadvertently entered an artery, causing tissue deterioration and gangrene in her arm. Ultimately, this resulted in the amputation of the plaintiff's arm, ending her career as a musician.

Phenergan's FDA-approved label stated, in enlarged, boldface type, that extreme care is required because injections that enter an artery may result in gangrene causing limb amputation. The plaintiff won a malpractice settlement against the health center clinicians, but also sued Phenergan's manufacturer, Wyeth, in state court, alleging that Wyeth should have revised its label to bar "IV-push" injections. The Vermont Supreme Court upheld a jury verdict of \$6.7 million against Wyeth (as reduced to account for the earlier settlement), ruling that Wyeth was obligated to comply with Vermont's common law duty not to use a particular form of "risky" drug administration, in this case, direct "IV-push" injection. Wyeth appealed the decision to the U.S. Supreme Court.

Wyeth's primary defense was that of pre-emption - - the "displacing" effect that federal law has on inconsistent or conflicting state laws - - mandated by the Supremacy Clause (Article VI, section 2) of the U.S. Constitution. In particular, Wyeth argued that a 2006 FDA regulation preamble expressing concern

about the impact that state failure-to-warn lawsuits may have on federal regulation should mean that such cases are pre-empted. The U.S. Supreme Court, however, disagreed.

Writing for a 6-3 majority, Justice John Paul Stevens upheld the plaintiff's state court victory. The Court framed the issue as "whether federal law pre-empts Levine's claim that Phenergan's label did not contain an adequate warning about using the IV-push method of administration." Stated differently, the case dealt with whether the medical experts at the FDA charged with this sort of regulation pre-empted state lawsuits by mandating and requiring clear and concise warning labels.

According to the U.S. Supreme Court, the answer to this question is "no." Relying heavily on Congressional intent, the majority decision points out that "[i]f Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point" during the 70-year history of the Food, Drug, and Cosmetic Act (which the FDA is charged with enforcing). The Court also noted that while an express pre-emption provision was enacted for medical devices, Congress has not enacted such a provision for prescription drugs. The majority believed that Congress' "silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence" that Congress did not intend for the FDA to be exclusively responsible for ensuring drug effectiveness and safety. In so holding, the Court allows lay juries in state tort suits to "uncover known drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly," in addition to "serv[ing] a distinct compensatory function that may motivate injured persons to come forward with information."

The decision is significant in a number of respects. At a minimum, it is clear from the decision that drug manufacturers, and not necessarily the FDA, are primarily responsible for ensuring that their warning labels are up to date, accurate, and complete. Furthermore, the Court makes it plain that the FDA must not only police the industry more closely (even while acknowledging that they lack the resources to do so), but must have Congressional mandate before it can quash plaintiffs' lawsuits in state courts that, in the words of the Court, "offer an additional, and important, layer of consumer protection that complements FDA regulation."

Arguably, Wyeth could not have done anything to avoid being sued. As noted in the dissent written by Justice Samuel A. Alito, Jr., "it is unclear how a 'stronger' warning label could have helped" the plaintiff, since the clinician who treated her "disregarded at least six separate warnings that are already on Phenergan's labeling." The outcome supported by the majority was simply that the jury's desire for a stronger warning on the Phenergan label regarding the dangers of IV-push trumped the FDA's view that the warning label was acceptable. In fact, the FDA had considered a stronger label proposed by Wyeth in 1998, but did not require it.

As the dissent cautions, this decision and the logic behind it, taken to its extremes, leads to the possibility that each and every drug (and other products) will have a multitude of different label warnings and use restrictions, perhaps one for every state in the Union (or more), which are periodically updated by local juries.

It is important to remember, however, that it is the FDA, and not state tort juries, that was authorized by Congress to determine when and under what circumstances a drug is “safe;” balancing the trade-offs between safety and efficacy is precisely the task that the FDA was established to perform. The alternative, now, is that some of these decisions will be made by lay juries, whose decisions are not explained to any degree and who are not accountable to anyone. The FDA, on the other hand, is highly accountable to Congress. Moreover, as suggested above, juries in different states and regions can make widely varying decisions on the same drug or product, leading to uncertainty and inconsistency that favors no one.

As explained in Justice Alito’s dissenting opinion, juries are by nature ill-equipped to handle the delicate cost-benefit balancing of the FDA. Instead of focusing on the overall benefit of the drug, device, or label thereon, or the people that reaped those benefits, juries focus solely on the risks or aspects of a particular product’s design or label that arguably contributed to a particular plaintiff’s injury. In contrast, the FDA has the benefit of the “long-view,” and can speak with “one voice,” rather than 50 or more.

Aside from the monetary impact the judgment has on Wyeth, the ruling has a significant trickle-down effect from the FDA, to health and drug companies, and ultimately to consumers on both economic and innovation fronts; namely, higher drug prices and disincentive to innovate. For instance, the uncertainty as to agency policy and the whims of lay juries may lead to less funding for start-up companies, and less research and development for new drugs, due to perceived legal risks. It may also increase the cost of new drugs, since prices will rise to account for the cost of future jury verdicts.

To summarize, by countermanding the FDA’s considered judgment that FDA-mandated warning labels are safe and placing that role in the hands of inexperienced jurors, the decision upsets the balances that the FDA strikes between the costs and benefits of drugs and their administration. Unless and until Congress authorizes FDA pre-emption for drug products at least under carefully prescribed conditions, this decision will have profound implications for the entire drug industry.

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